REMARKS

Upon receipt of the final Office Action, mailed December 29, 2008, Claims 1, 3, 5-6 and 8-74 were pending. Claims 16-56 were previously withdrawn from consideration as being directed to non-elected subject matter.

In the final Office Action, Claims 1, 3, 5-6, 8-15 and 57-74 were rejected, as discussed in more detail below.

Claims 1, 13, 14, 61, 66, 68, 69 and 74 are amended herein, as discussed in more detail below. Claims 57-60 and 70-73 are cancelled herein without prejudice. In addition, previously withdrawn Claims 16-56 are cancelled herein in the interest of furthering the allowance of this application. In cancelling Claims 16-56, Applicants retain the right to file divisional applications on any non-elected subject matter recited therein.

Reconsideration of the claimed subject matter of Claims 1, 3, 5-6, 8-15, 61-69 and 74 in view of the following remarks is therefore respectfully requested.

Rejection of Claims 1, 3, 5, 6, 8-15 and 57-74 under 35 USC 112, ¶ 1

The Examiner maintained the rejection of claims 1, 3, 5, 6, 8-15 and 57-74 under 35 U.S.C. 112, ¶ 1, for the reasons stated in the previous Office Action. In so doing, the Examiner contended that Applicants' arguments filed on September 2, 2008 had been fully considered but were not found to be persuasive. In particular, the Examiner contended that:

> *Applicants argue that not all of the rejected claims require the presence of water and/or a therapeutically effective amount of iron because claims 61-67 are specifically directed to a "dry" dialysate precursor composition which does not comprising [sic] water or a therapeutically effective amount of iron. This is not found to be persuasive because the claims 61-67 drawn to "comprising" does not exclude water or iron and that claim 68 depend from claim 61 further defines what is the element comprised by claim 61. Applicants argue that the specification pages 20-21 disclose which forms of iron are considered to be compatible. This is not found to be persuasive because the disclosures in the specification has been carefully reviewed and considered. It refers the term "iron" as both ferric and ferrous form of iron as well as complexes of iron particularly iron dextran and that "ferric" form such as "ferric gluconate", another iron complex that requires a great deal of time and skill for administration. However, the "Ash" (WO 98/06482A1) reference teaches that iron dextran causes severe allergic reactions, fever and rashes during injection and that only about half of iron in the iron dextran is bioavailable. Therefore, it is highly speculative that any type of iron would work as a precursor dialysate to serve as a dialysate composition without undue experimentation. Therefore, a dialysate precursor composition comprising citrate at a concentration raging from about 20 to about 900 mEq/L; a buffering anion selected from acetate and/or lactate; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; at least one physiologically-acceptable cation; and a therapeutically*

effective amount of iron is not considered to be enabled by the instant specification. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claims 57-60 and 70-73 are cancelled herein, thereby rendering moot this rejection with respect to these claims. Applicants respectfully traverse this rejection with respect to Claims 1, 3, 5, 6, 8-15, 61-69 and 74 for the reasons set forth in the previous response and for the following additional reasons:

Applicants have amended Claims 61-69 and 74 to recite that the dry dialysate precursor compositions therein consists essentially of the recited components. The transitional phrase "consisting essentially of" allows for non-recited components which do materially affect the basic and novel characteristic of the claimed composition. Given that the preamble in these claims specifically recites that the claimed composition is a "dry" composition, Applicants respectfully submit that the inclusion of water as a non-recited component in these claims would materially affect the basic characteristic of the claimed composition of being a "dry" composition. Accordingly, Applicants respectfully request the withdrawal of this aspect of the rejection with respect to Claims 61-69 and 74. Applicants note that, in making this amendment, Claims 66, 68 and 74 were also amended to be in independent form in order to recite additional components (the ferric form of iron for Claims 66 and 68 and one or more trace elements for Claim 74).

Furthermore, Applicants have amended the rejected generic claims to be directed to dialysate precursor compositions wherein the iron is present in a therapeutically effective amount of a ferric form of iron (see amended Claims 1, 13, 68 and 74). Applicants have also amended the relevant dependent claims (see amended Claims 14 and 69) to be directed to dialysate precursor compositions wherein the ferric form of iron present therein is ferric citrate. These amendments are fully supported by the specification as originally filed. Accordingly, Applicants respectfully request the withdrawal of this aspect of the rejection with respect to Claims 1, 3, 5, 6, 8-15, 61-69 and 74.

Applicants further note that the Examiner specifically stated in the final Office Action that the specification was considered enabling for a dialysate precursor composition comprising citrate at a concentration ranging from about 20 to about 900 mEq/L; a buffering anion selected from acetate and/or lactate; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; at least one physiologically-acceptable cation; and a therapeutically effective amount of a **specific form of iron.**" Accordingly, in view of the foregoing amendments to the claims wherein a specific form of iron is recited, *i.e.*, the **ferric** form of iron, Applicants respectfully submit that the specification is clearly enabling of Claims 1, 3, 5, 6, 8-15, 61-69 and

74, particularly Claims 14 and 69, which recite that the ferric form of iron is present as **ferric citrate**. Furthermore, a therapeutic effective amount of the ferric form of iron is specifically stated in the specification to be from about 0.1 to 300 micrograms/deciliter of the final dialysate composition (see page 21). As previously noted, one skilled in the dialysis field could easily calculate the suitable concentration of the ferric form of iron in the claimed dialysate precursor compositions from this statement and from the knowledge that one skilled in the dialysis field would have with respect to suitable concentrations of iron in dialysate compositions which do not contain citrate and a buffering anion[1].

Accordingly, in view of the foregoing remarks and the remarks presented in the previous response, Applicants respectfully submit that one skilled in the dialysis field would not have to resort to undue experimentation in order to make and use the claimed iron-containing dialysate precursor compositions. Withdrawal of the rejection of 1, 3, 5-6, 8-15, 61-69 and 74 under 35 U.S.C. 112, ¶1, is therefore respectfully requested.

Supplemental Information Disclosure Statement

Filed herewith is a Fifth Supplemental Information Disclosure Statement (IDS). The references listed in this Fifth Supplemental IDS have been considered in related U.S. and foreign applications and are being submitted herein for completion of the record of the instant application. Entry of this Fifth Supplemental IDS is therefore respectfully requested.

The Director is authorized to charge any additional fees due by way of this Submission, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,
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[1] See, for example, the teachings of previously cited reference PCT Published Patent Application WO 98/06482 ("Ash").